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| 20995 | 7590 | 12/03/2009 | EXAMINER | |
| KNOBBE MARTENS OLSON & BEAR LLP | | | PENNY, TABATHA L | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/583,024 | IVERSEN ET AL. |
| | Examiner | Art Unit |
| | TABATHA PENNY | 4171 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 15 June 2006.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 148-219 is/are pending in the application.
 4a) Of the above claim(s) 158-219 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 148-157 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 15 June 2006 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>7/14/2009, 5/5/2009, 8/7/2008, 2/27/2007,</u> <u>11/20/2006</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This is the first action on the merits.
2. Claims 148-219 are pending.
3. The preliminary amendment filed 6/15/2006 has been entered and fully considered.

Election/Restrictions

4. Claims 158-219 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/05/2009.

Priority

5. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has complied with conditions for receiving the benefit of an earlier filing date.
6. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Drawings

9. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "1", "2", "3", "4", "5", "6", and "7" have been used to

designate both a fluid storage vessel and a alcohol introduction point, a compressor and a reactor outlet, a heat exchanger and a solvent, a precursor introduction point and an anode, a reactor vessel and a cathode, a separator and a voltage generator, a discharge stream and a vent respectively. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

10. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 7 in Figure 7. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the

examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

11. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. **It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.**

12. Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:

- (1) if a machine or apparatus, its organization and operation;
- (2) if an article, its method of making;
- (3) if a chemical compound, its identity and use;

- (4) if a mixture, its ingredients;
- (5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

Claim Rejections - 35 USC § 112

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 150-152 and 154-155 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

15. **Regarding claims 150-152 and 154-155**, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

16. **Regarding claims 150-152 and 154-155**, a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions

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of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 150, 151, 152, 154, and 155 recite the broad recitations 100 nanometers, 60%, 20 nanometers, 85-500 bar, and 20-500°C respectively, and the claims also recite "such as" 30 nanometers, 40%, 10 nanometers, 100-300 bar, 30-450°C respectively which are the narrower statements of the range/limitation.

17. **Claim 150** recites the limitation "nanoscaled primary particles" in Claim 148. There is insufficient antecedent basis for this limitation in the claim. For purposes of examination "said nanoscaled primary particles" will refer to the "primary particles" of claim 148.

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

19. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

20. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

21. Claims 148-157 rejected under 35 U.S.C. 103(a) as being unpatentable over WATKINS et al. (US 5,789,027) in view of GUPTA et al. (US 2002/0000681).

22. **Regarding claim 148**, WATKINS et al. discloses a method of depositing a film of material on the surface of a substrate, i.e. producing a fine particle material, comprising: dissolving a precursor of the material into a supercritical solvent (abstract), i.e. at least one of the fluids being in a supercritical state before or after being introduced into said vessel, in a vessel (col. 8 line 15), i.e. introducing one or more substances contained in one or more fluids into a vessel by introducing said fluids into the vessel; exposing the substrate to the solution under conditions at which the precursor is stable (abstract), i.e. said vessel containing one or more sections comprising a material; initiating a chemical reaction (abstract), i.e. wherein at least one of said substances undergoes a chemical reaction; wherein at least one of said substances undergoing a chemical reaction is an alkoxide (col. 7 lines 41-43); wherein said alkoxide comprises a metal (col. 7 lines 41-

43); wherein the method further comprises: introducing into the reaction vessel at least one reaction reagent (abstract), i.e. initiator for said chemical reaction.

23. WATKINS et al. does not appear to explicitly disclose subsequently introducing into the vessel said one or more substances dissolved and /or dispersed in at least one fluid.

24. However, GUPTA et al. discloses a method of producing a coated core particle (para. [0107]) wherein the mixture is mixed with a solution containing a desired substance, i.e. one or more substances dissolved and/or dispersed in at least one fluid are introduced to the vessel.

25. At the time of the invention, it would have been *prima facie* obvious to one of ordinary skill in the art to modify the method, of WATKINS et al., to include the additional substance dissolved in a fluid, as taught by GUPTA et al., in order to obtain a coated fine particle material.

26. **Regarding claim 149**, WATKINS et al. does not appear to explicitly disclose the reactions are sol-gel reactions.

27. However, WATKINS et al. discloses the same reactants in the same reactions under the same process conditions as applicants' (col. 1 lines 53-62). Therefore, Watkins et al. inherently discloses the reactions are sol-gel reactions.

28. **Regarding claim 150**, WATKINS et al. discloses the primary particles are 80-100 nanometers. "In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. In re Wertheim, 541

F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990).” MPEP 2144.05.

29. **Regarding claim 151 and 152**, WATKINS et al. is silent as to the standard deviation of the size distribution of the primary particles.

30. However, GUPTA et al. discloses various particle sizes and standard deviations, such as 96 nm size with 43 nm standard deviation, or **45%** of the average size of the primary particles (para. [0131]); 30 nm size with **13 nm** standard deviation, or **43%** of the average size of the primary particles (para. [0133]); and 0.28 um size with 0.13 um standard deviation, or **46%** of the average size of the primary particles (para. [0139]). “In the case where the claimed ranges “overlap or lie inside ranges disclosed by the prior art” a *prima facie* case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990).” MPEP 2144.05.

31. At the time of the invention, it would have been *prima facie* obvious to one of ordinary skill in the art to include the particle size distribution, of GUPTA et al., with the method of WATKINS et al. in order to obtain an appropriate sized nanoparticle suitable for use in a particular industry (GUPTA et al. para. [0004]).

32. **Regarding claim 153**, WATKINS et al. discloses wherein at least one of said fluids being in a supercritical state is carbon dioxide (col. 6 lines 42-43).

33. **Regarding claim 154**, WATKINS et al. discloses wherein the pressure of at least one of said fluids is in the range of 50-500 bar (col. 5 line 36). “In the case where the claimed ranges “overlap or lie inside ranges disclosed by the prior art” a *prima facie*

case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990)." MPEP 2144.05.

34. **Regarding claim 155**, WATKINS et al. discloses wherein the temperature in the vessel is maintained 100-250°C (col. 7 line 23). "In the case where the claimed ranges overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990)." MPEP 2144.05.

35. **Regarding claim 156**, WATKINS et al. discloses wherein the fluid further comprises at least one co-solvent (col. 5 lines 58-61).

36. **Regarding claim 157**, WATKINS et al. further discloses precipitation is provided by a change of solubility which is due to expanding one of said fluids containing at least one of said substances in the vessel (col. 8 lines 15-20).

37. WATKINS et al. does not appear to explicitly disclose the change in solubility is due to an antisolvent present in the vessel.

38. However, GUPTA et al. discloses a method of precipitating micron or nanometer size particles wherein a dispersion containing the substance of interest is contacted with an antisolvent (para. [0004]). GUPTA et al. further discloses the method produces very small particles having a narrow size distribution (para. [0025]).

39. At the time of the invention, it would have been *prima facie* obvious to one of ordinary skill in the art to modify the method of WATKINS et al. to include the antisolvent, as taught by GUPTA et al., in order to obtain very small particles having a

narrow size distribution for use in designing drug delivery systems for controlled release and targeting in the pharmaceutical industry (para. [0006]).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TABATHA PENNY whose telephone number is (571)270-5512. The examiner can normally be reached on Monday thru Friday 8:00am-4:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Barbara Gilliam can be reached on (571)272-1330. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/tp/

/PATRICK NOLAN/
Supervisory Patent Examiner, Art Unit 4171